(10) The name, title, address, telephone number, and signature of the person who prepared the report.

§ 804.30 Annual certification.

Distributors required to report under this section shall submit a certification report to FDA by the date designated for annual registration for the firm in § 807.21 of this chapter. This date will cover the period ending 1 month before the month of the scheduled date of mailing as indicated in § 807.21(a). The report will contain the following information:

(a) The name, address, telephone number, and FDA registration number of the distributor;

(b) A statement certifying that:

(1) The distributor listed in paragraph (a) of this section has filed reports under this section during the previous 12-month period and all MDR reportable events have been submitted to FDA and/or to the appropriate manufacturer. The report will also include the number of death, serious injury or serious illness reports that were submitted to FDA, and the number of malfunction reports that were submitted to manufacturers; or

(2) The distributor listed in paragraph (a) of this section did not receive any reportable events during the previous 12-month period.

(c) The name, address, title, telephone number, and signature of the individual making the certification for the firm. This person must be a responsible person designated by the firm.

§ 804.31 Additional requirements.

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

§ 804.32 Supplemental information.

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

§ 804.33 Alternative reporting requirements.

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting re-